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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,164

08/30/2006

Naoki Nagahara

2006_1328A

6045

513

7590

11/21/2008

WENDEROTH, LIND & PONACK, L.L.P.

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SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,164	Applicant(s) NAGAHARA ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-12 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/24/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 8/7/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 102/103

The rejection of Claims 1-2, 7-12, and 15 under 35 U.S.C. 102(e) as being anticipated by US 20050181052 ('052) is maintained. The rejection of Claims 4 and 16-24 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) is maintained. The rejection of Claim 5 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) in view of US 5665348 ('348) is maintained.

Applicant argues that '052 is limited to a gelatin capsule and the Examples disclose only a hard gelatin capsule. Such a hard gelatin capsule, or a HPMC capsule which has as problem that solubility is low at low pH is excluded from the present invention. Instant Claim 1-6 refer to the capsule itself, and not to the contents of the capsule.

Applicant's arguments have been fully considered but are not found persuasive. The features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification,

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limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). There is no requirement in the claims that hard gelatin capsules are excluded from the invention. It should be noted that in the disclosure of '052, hard gelatin capsules are only one preferred and non-limiting embodiment of the invention (see paragraph 63). For the reasons set forth in the previous office action, the capsule preparation disclosed by '052 is stable in a low moisture state and has pH-independent disintegration properties. The capsule preparation disclosed by '052 thus meets every limitation of the instant claims. Regarding the exclusivity of the term "capsule" as recited in Claims 1-6 to refer to the capsule (i.e. the capsule shell), and not the contents, the Examiner must give the claims their broadest reasonable interpretation. There is no limiting definition of "capsule" provided in the specification, and a capsule as recited in Claims 1-6 reasonably encompasses the entire capsule, including the capsule shell and contents, not the capsule shell only. Thus, in the broadest reasonable interpretation, both the capsule shell and the capsule contents together constitute the capsule.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number

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is (571)270-3499. The examiner can normally be reached on Mon-Thurs
9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the
examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616.
The fax phone number for the organization where this application or proceeding
is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from
the Patent Application Information Retrieval (PAIR) system. Status information
for published applications may be obtained from either Private PAIR or Public
PAIR. Status information for unpublished applications is available through
Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR
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free). If you would like assistance from a USPTO Customer Service
Representative or access to the automated information system, call 800-786-
9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

November 18, 2008